REMARKS/ARGUMENTS

The rejections presented in the final Office Action dated January 26, 2006 (hereinafter Office Action) have been considered. Claims 1-35 remain pending in the application. Reconsideration of the pending claims and allowance of the application in view of the present response is respectfully requested.

Claims 1, 3, 6, 8, 11-14, 16, 19, 21, 24, 25, 27, 30, 31 and 33 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,728,140 to *Salo et al.* (hereinafter "*Salo*") in view of U.S. Patent No. 5,545,210 to *Helland et al.* (hereinafter "*Helland*"). Claims 2, 4, 7, 9, 15, 17, 20, 22, 26, 28, 32 and 34 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Salo* in view of *Helland* and further in view of U.S. Patent No. 5,931,862 to *Carson.* (hereinafter "*Carson*"). Claims 5, 10, 18, 23, 29 and 35 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Salo* in view of *Helland* and further in view of *Stokes*.

Applicant has carefully considered the Examiner's Response to Arguments presented on page 2 of the Office Action. Applicant respectfully disagrees with the Examiner's characterization of the asserted references, particularly *Salo*, and provides the following discussion to further enhance an understanding of Applicant's claimed invention relative to the asserted reference combinations.

Each of Applicant's independent claims, 1, 6, 14, 19, 24, and 30 recites, in some form, a pacing electrode having a fluoropolymer coating or sleeve provided on a majority of an exposed surface of the electrode sufficient in coverage to inhibit exit block development.

The Examiner contends that the "reading of *Salo* to have a majority, i.e., the proximal end of the electrode (helix), covered with insulation, is certainly within the scope of the claims a written." Respectfully, this characterization of *Salo* is in error,

The "exposed surface of the electrode" in Applicant's claims, when read in light of Applicant's specification, refers to the tissue stimulating surface of the electrode, as was previously discussed in the prior responsive communication. For example, Applicant's specification on page 11, lines 8-15 teaches that:

> Referring to Figure 3A, the helical electrode 420 includes a polymer layer 425. The polymer layer 425 may be a coating or sheath, such as, for example, silicon tubing, a PTFE or ePTFE coating, or other layer adapted to reduce the tissue body response to the helical electrode 420. The polymer layer 425 thereby typically covers most or all of the exposed helical electrode 420, but may alternately include voids, apertures, or other discontinuities. The polymer layer 425 solicits less tissue inflammation and reduces the amount of fibrotic tissue around the implant site, reducing exit block development. (*emphasis added*)

One skilled in the art would readily understand that Applicant's exposed electrode surface provided with a fluoropolymer coating or sleeve defines a tissue stimulating surface of the electrode. For example, tissue stimulation vis-à-vis Applicant's coated helical electrode is provided even where the entirety of the exposed helical electrode 420 is covered by polymer layer 425 according to Applicant's disclosure and claims.

This clearly would not be the case if the "insulation" taught in *Salo* coated the entirety of the bare electrode surface of *Salo*. *Salo* teaches that the insulation on its electrode is necessary so that the electrode provides no tissue stimulation to the right ventricular wall (due to the presence of the "insulation"), yet provides cardiac stimulating pulses to the left ventricle independent of the right ventricle (due to the presence of the bare electrode surface proximate the left ventricular septal wall). *See, e.g.*, column 1, lines 51-67 of *Salo*.

Salo clearly teaches that the portion of its electrode covered by insulation does not define a tissue stimulating portion of the electrode. *Salo* explicitly defines its "electrode surface" as the bare distal convolutions shown in the Figures and described in the text (*see, e.g.*, column 1, lines 59-62). The covered portion of the *Salo* electrode can not define a tissue stimulating surface, as this would frustrate the purpose of the disclosed electrode (i.e., this would result in stimulating both the right and left ventricles, which the *Salo* electrode is designed to avoid).

Thus, the only portion of the *Salo* electrode that defines a tissue stimulating surface is the bare distal convolutions. *Salo* teaches that these distal convolutions are bare (i.e., not covered), and are clearly not covered by a fluoropolymer coating or sleeve.

Helland does not cure the deficiencies of *Salo*. As set forth in Applicant's prior responsive communications, *Helland* does not teach or suggest a coating or sleeve provided on a majority of the exposed surface of the fixation arrangement. *Helland* discloses a bipolar active fixation lead having a helix 44 defining an inner electrode 46, an intermediate insulator 48, and an outer electrode 50, as shown in Figures 3-5 of *Helland*. The outer and central electrodes 50, 46 operate as a bipolar electrode pair. As can be seen in Figures 3-5 of *Helland*, the intermediate insulator 48 does not cover a majority of the exposed surface of the fixation member. The inner 46 and outer 50 electrodes form the majority of the exposed surface of *Helland's* fixation member and these elements are not covered by the insulator.

Salo expressly teaches that the electrode is not covered by insulation (see above argument concerning independent stimulation of left and right ventricles). It is improper to combine references where the references teach away from their combination. *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983). The references cited by the Examiner fail to suggest the desirability of the combination and provide no motivation to make the asserted combination as required to establish a *prima facie* case of obviousness. For at least these reasons, claims 1, 3, 6, 8, 11-14, 16, 19, 21, 24, 25, 27, 30, 31, and 33 are patentable over the combination of *Salo* and *Helland*.

Neither *Salo* nor *Helland* teaches or suggests all of the claims limitations of Applicant's claims. Because the references cited by the Examiner do not teach or suggest all of the claim limitations, Applicant's claims 1, 3, 6, 8, 11-14, 16, 19, 21, 24, 25, 27, 30, 31, and 33 are patentable over the combination of *Salo* and *Helland*.

Claims 2, 4, 7, 9, 15, 17, 20, 22, 26, 28, 32, and 34 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Salo* in view of *Helland* and in further view of Carson, US 5,931,862. Claims 5, 10, 18, 23, 29, and 35 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Salo*, in view of *Helland*, and in further view of Stokes, H356.

Each of the above-listed obviousness rejections relies on the teachings of *Salo* and *Helland*. Applicant asserts that the additional references, when combined with *Salo* and *Helland*, fail to render the claims listed above unpatentable. A *prima facie* case of obviousness requires that the asserted references teach or suggest all of the claim elements. In each of the combinations asserted above, none of the asserted references (*Salo*, *Helland, Carson, Stokes*) teaches or suggests, for example, an electrode having a fluoropolymer coating or sleeve provided on a majority of an exposed surface of the electrode.

Neither *Salo* nor *Helland* describes this element for the reasons discussed above. *Carson* expressly teaches that portions of lead 12 not covered by the sheath include the distal pacing electrode 20, which is shown to include a helix or tine fixation element. *See Carson*, column 4, lines 34-36. *Stokes* describes a pacing lead that has a bore for passage of a drug to the stimulation and fixation site. The fixation element in *Stokes* does not have a coating or sleeve. Because, for each rejection made by the Examiner, the cited references do not teach or suggest all of the claim limitations of Applicant's invention, claims 2, 4, 5, 7, 9, 10, 15, 17, 18, 20, 22, 23, 26, 28, 29, 32 and 35 are patentable over the asserted combinations.

It is to be understood that Applicant does not acquiesce to Examiner's characterization of the asserted art or Applicant's claimed subject matter, nor of the Examiner's application of the asserted art or combinations thereof to Applicant's claimed subject matter. Applicant reserves the right to address in detail the Examiner's characterizations, conclusions, and rejections in future prosecution.

It is believed that the pending claims are in condition for allowance and removal of the finality of the rejection is respectfully requested. The Examiner is invited to contact Applicant's Representatives, at the below-listed telephone number, if there are any questions regarding the above new claims or if prosecution of this application may be assisted thereby.

Authorization is given to charge Deposit Account No. 50-3581 (GUID.076PA) any necessary fees for this filing. If the Examiner believes it necessary or helpful, the undersigned attorney of record invites the Examiner to contact him at to discuss any issues related to this case.

Respectfully submitted,
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